SURGICAL PRACTICES IN SASKATCHEWAN:

RESEARCHING A SURGEON'S PERCEPTION OF TOTAL MESORECTAL EXCISION

A thesis submitted to

The College of Graduate Studies and Research,

In partial fulfillment of the requirements for the

Master's Degree in the

Department of Health Sciences,

Clinical Investigator Program,

At the University of Saskatchewan

Saskatoon, SK, Canada

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KEYWORDS:

Rectal cancer, rectal carcinoma, rectal neoplasm, colorectal cancer, colorectal carcinoma, cancer, carcinoma, total mesorectal excision (TME), surgeon perception

ABSTRACT

Background: Meticulous rectal cancer surgery is imperative in the treatment of rectal cancer. Total mesorectal excision (TME) is required to decrease local recurrence and improve overall survival after surgical resection of rectal cancer.

Purpose: The purpose of this study is to evaluate a surgeon's perception of TME by asking surgeons to predict the pathology results of surgeries they perform prior to obtaining pathology data.

Hypothesis: It is hypothesized that the majority of surgeons are accurately perceiving and performing complete TMEs, during rectal cancer resections. We would like to quantify the accuracy of the surgeon's perception of complete total mesorectal excisions.

Objectives:

(1) To determine if a surgeon's perception of completeness of excision correlates with pathology data. If so, to quantify the accuracy of the surgeon's perception of complete TMEs.

(2) To determine which factors affected a surgeon's ability to obtain a complete resection.

Patients and methods: A prospective study on all adult rectal cancer patients in Saskatchewan from August 2014 to August 2016, including a total of 16 patients.

Results: Data analysis was performed using a kappa agreement calculation. The calculation was performed using a cross tabulation of surgeon prediction of TME as nearly complete or complete versus pathology results of nearly complete, complete or incomplete. There were a total of 16 cases and specimens analyzed. The data demonstrated a kappa value of 0.067 which corresponds with a p-value of 0.733, suggesting poor and non-significant correlation between surgeon prediction of completeness of total mesorectal excision and pathology result.

ACKNOWLEDGEMENTS

I would like to thank my supervisor, Dr. Gary Groot for all his assistance over the course of the developing this research project. Your support, guidance, and direction have been of utmost importance in my growth as a researcher. It has been a privilege to work with you.

I would also like to thank the members of my research advisory committee, including, Dr. Angela Busch, Dr. Raymond Deobald, Dr. Christopher Kenyon, and Dr. Fergall Magee. Your advice, guidance and support was immeasurable and greatly appreciated.

Several University of Saskatchewan departments have been instrumental in the completion of this degree including the Division of General Surgery, Department of Surgery, Health Sciences Department, and the Clinical Investigator Program.

I would like to acknowledge the financial support I received from Dr. Groot's research fund, Dr. Miller's research fund, the Division of General Surgery, the Department of Surgery, and the Clinical Investigator Program.

Thanks to the operative staff for aiding in examining the operative slates for this research. Thank you to the Bonnie Korthuis and Michelle McCarron in assistance with the Research Ethics Board application. Caitlin Carter, the Client Services Librarian at the Regina Qu'Appelle Health Region Library, was a great help in performing a literature review on Total Mesorectal Excisions. Thank you to Angie Zoerb, Graduate Program Coordinator, for all of your support and help during my project. Also, thanks to the Clinical Research Support Unit, under the supervision of Dr. June Lim, for their assistance in data analysis.

DEDICATION

Thank you to all those who have supported me and those who continue to support me throughout my educational career.

I dedicate this thesis to those who are currently trying to advance their own knowledge to positively grow as a person.

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ABBREVIATION	DESCRIPTION
AJCC	American Joint Committee on Cancer
APR	Abdominoperineal resection
AR	Anterior resection
CAA	Coloanal anastomosis
CAP	College of American Pathologists
CRC	Colorectal cancer
CRM	Circumferential radial margin
CRT	Chemoradiotherapy
CRU	Clinical Research Unit
FIT	Fecal immunochemical test
FOBT	Fecal-occult blood test
IHC	Immunohistochemistry
LAR	Low anterior resection
MRN	Medical record number
PHN	Personal health number
PME	Partial mesorectal excision
SPCRC	Saskatchewan Screening Program for Colorectal Cancer
TME	Total mesorectal excision
TNM	Tumour, lymph node metastasis, distant metastasis classification
UICC	Union for International Cancer Control
REB	Research ethics board

INTRODUCTION

Rectal cancer is a common cause of morbidity and mortality amongst Canadians. Optimally, rectal cancer is diagnosed and treated early in the disease course to improve outcomes. Often the treatment of rectal cancer is multifaceted combining a multidisciplinary approach amongst primary care physicians, screening programs, radiology, surgical oncology, medical oncology, radiation oncology, pathology, and other health care professionals. Surgery remains one of the mainstays of treatment for rectal cancer. The surgical approach, utilizing total mesorectal excision (TME), has been shown to decrease local recurrence and improve overall survival (Washington et al, 2013).

This study aims to investigate the mesorectal excisions performed for rectal cancer surgeries across four hospitals within Saskatchewan, Canada. The purpose of this study is to evaluate a surgeon's perception of total mesorectal excision by asking surgeons to predict the pathology results of surgeries they perform prior to obtaining pathology data.

The study involved two phases of data collection. First, survey data was collected from surgeons and second, patient information was collected along with pathology data. It is hypothesized that the majority of surgeons are accurately perceiving and performing complete mesorectal excisions, during rectal cancer resections. We would like to quantify the accuracy of the surgeon's perception of complete mesorectal excision. Therefore, there are two main objectives of this study. The first objective is to determine if a surgeon's perception of completeness of excision correlates with pathology data. If so, the goal is to quantify the accuracy of the surgeon's perception of complete TMEs. The second objective is to determine which factors may have affected a surgeon's ability to obtain a complete resection.

LITERATURE SURVEY

CANADIAN CANCER STATISTICS

Cancer remains a large cause of morbidity and mortality amongst Canadians. Statistics from the Canadian Cancer Society for 2015 state that approximately 2 in 5 Canadians will develop cancer in their lifetime and approximately 1 in 4 Canadians will die of cancer (Canadian Cancer Society, 2015). Furthermore, for 2015 it is estimated that 196,900 people will be diagnosed with cancer and 78,000 Canadians will die of cancer with the year (Canadian Cancer Society, 2015). As of 2015, colorectal cancer is the 2nd most common cancer in Canadian males and 3rd most common cancer in Canadian females, representing 13.9% and 11.5% of new cases, respectively (Canadian Cancer Society, 2015). In 2015, it is estimated that there will be 25,100 new cases of colorectal cancer in Canada, with 14,000 male patients and 11,100 female patients (Canadian Cancer Society, 2015).

Estimated new cases for the most common cancers by age group and sex, Canada, 2015

	Lung			Colorectal			Prostate	Breast
Age	Total*	Males	Females	Total*	Males	Females	Males	Females
All ages	**26,600**	**13,600**	**13,000**	**25,100**	**14,000**	**11,100**	**24,000**	**25,000**
0–19	10	5	5	10	5	5	—	5
20–29	25	10	15	80	40	40	—	120
30–39	90	30	60	310	160	150	5	1,050
40–49	640	270	370	1,100	570	520	460	3,300
50–59	3,700	1,700	1,950	3,700	2,100	1,550	4,400	6,200
60–69	7,900	4,100	3,800	6,700	4,100	2,600	9,600	6,800
70–79	8,400	4,500	3,900	7,000	4,100	2,900	6,400	4,500
80+	5,900	3,000	2,900	6,200	2,900	3,300	3,100	3,100

Table 1.1: **Estimated new cases for the most common cancers in Canada, 2015**

(Canadian Cancer Society, p. 34, 2015)

Out of all the estimated new cases of colorectal cancers diagnosed in Canada, a total of with 770 of these patients are estimated to be from Saskatchewan, with 430 male patients and 340 female patients (Canadian Cancer Society, 2015).

Estimated new cases for selected cancers by sex and province, Canada, 2015

	Canada*	BC	AB	SK	MB	ON†	QC‡	NB	NS	PE	NL‡
Males											
All cancers	**100,500**	**13,400**	**9,000**	**2,800**	**3,400**	**38,300**	**24,900**	**2,800**	**3,300**	**510**	**1,950**
Prostate	24,000	3,800	2,200	690	740	9,700	4,600	780	710	140	540
Colorectal	14,000	1,750	1,250	430	540	5,100	3,700	370	510	65	330
Lung	13,600	1,550	1,100	360	430	4,600	4,300	430	480	75	280
Bladder	6,200	890	610	200	220	1,650	2,000	180	230	30	100
Non-Hodgkin lymphoma	4,500	640	440	140	150	1,750	1,000	110	140	15	85
Kidney	3,900	350	360	120	160	1,500	1,000	140	150	20	75
Melanoma	3,700	550	320	75	110	1,750	510	95	160	25	50
Leukemia	3,500	490	350	120	140	1,450	730	85	80	15	35
Oral	2,900	380	260	65	120	1,200	680	65	90	15	45
Pancreas	2,400	330	220	70	85	910	650	65	65	10	30
Stomach	2,100	270	200	65	90	780	540	55	65	10	55
Brain/CNS	1,750	200	150	45	50	740	440	35	50	5	25
Esophagus	1,700	210	200	40	50	700	350	45	55	10	20
Liver	1,650	250	150	25	40	700	410	20	40	5	15
Multiple myeloma	1,500	190	140	40	45	600	370	35	45	5	20
Thyroid	1,450	120	130	20	35	680	360	35	30	5	15
Testis	1,050	150	110	30	40	410	230	20	25	5	10
Females											
All cancers	**96,400**	**12,000**	**8,000**	**2,700**	**3,300**	**37,700**	**25,200**	**2,300**	**3,000**	**400**	**1,550**
Breast	25,000	3,400	2,300	710	860	9,800	6,100	570	780	110	360
Lung	13,000	1,600	1,050	410	460	4,400	4,000	380	480	60	190
Colorectal	11,100	1,400	910	340	430	4,100	2,900	260	410	55	230
Body of uterus	6,300	870	540	170	250	2,600	1,450	140	160	25	95
Thyroid	4,800	300	370	50	100	2,500	1,200	110	90	10	40
Non-Hodgkin lymphoma	3,700	510	360	110	140	1,450	810	95	120	15	70
Melanoma	3,100	460	260	65	80	1,500	440	90	140	15	35
Ovary	2,800	310	190	80	100	1,200	700	65	65	10	30
Leukemia	2,700	340	260	85	80	1,200	540	50	60	10	20
Pancreas	2,400	310	220	75	80	860	660	70	80	10	25
Kidney	2,300	200	220	75	80	950	580	80	100	15	50
Bladder	2,100	290	180	70	70	510	750	65	75	10	35
Cervix	1,500	180	170	45	50	640	290	30	45	10	30
Oral	1,450	180	110	35	55	610	350	30	40	10	15
Stomach	1,250	140	85	35	40	510	330	35	40	5	30
Brain/CNS	1,250	150	110	35	40	490	360	30	40	5	20
Multiple myeloma	1,150	140	110	35	35	480	270	30	30	5	15
Liver	550	85	55	10	15	190	160	5	10	—	5
Esophagus	500	75	50	15	15	200	110	10	20	—	5

Table 1.2: Estimated new cases for selected cancers by sex and province in Canada, 2015

(Canadian Cancer Society, p. 36, 2015)

This equates to 1 in 14 Canadian males and 1 in 16 Canadian females being diagnosed with colorectal cancer during their lifetime (Canadian Cancer Society, 2015). Thus, many patients will also die from colorectal cancer. The percent distribution of estimated cancer deaths by sex

for 2015, show 12.4% of male deaths and 11.5% of female deaths will result from colorectal cancer (Canadian Cancer Society, 2015).

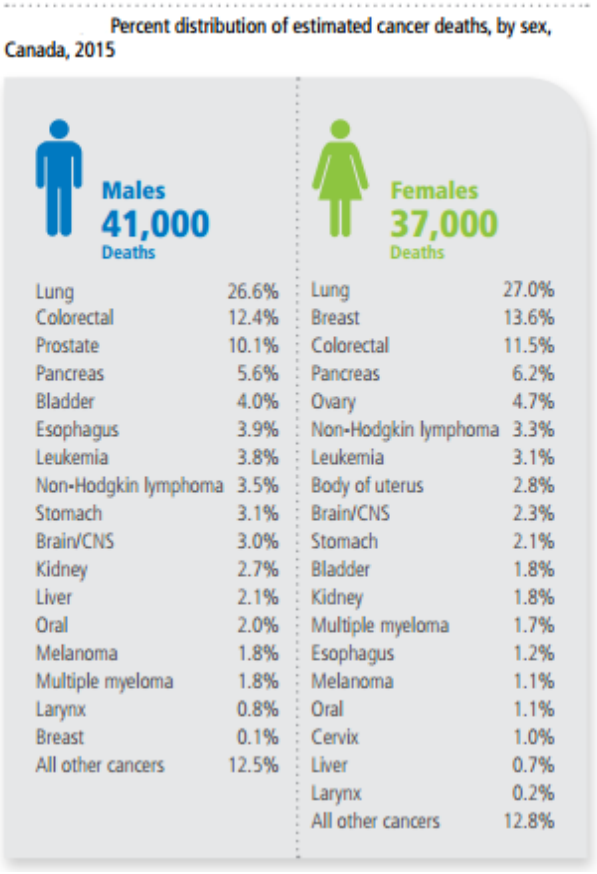

Figure 1.1: **Percent distribution of estimated cancer deaths in Canada for 2015**

(Canadian Cancer Society, p. 39, 2015)

Therefore, colorectal cancer is a relatively common malignancy amongst the Canadian population. The significance of understanding how to optimize treatment of colorectal cancer, is consequently, of utmost importance.

COLORECTAL CANCER SCREENING

Currently, there have been many colorectal screening programs implemented across Canada to identify patients with premalignant polyps and colorectal cancers. In Saskatchewan,

the Saskatchewan Screening Program for Colorectal Cancer (SPCRC) is a program developed by the Saskatchewan Cancer Agency to screen for colorectal cancer (Saskatchewan Cancer Agency, 2015). Fortunately, the mortality rates for colorectal cancer, in both women and men have been steadily declining in Canada from 1986 until 2015. The following tables illustrate this for both females and males.

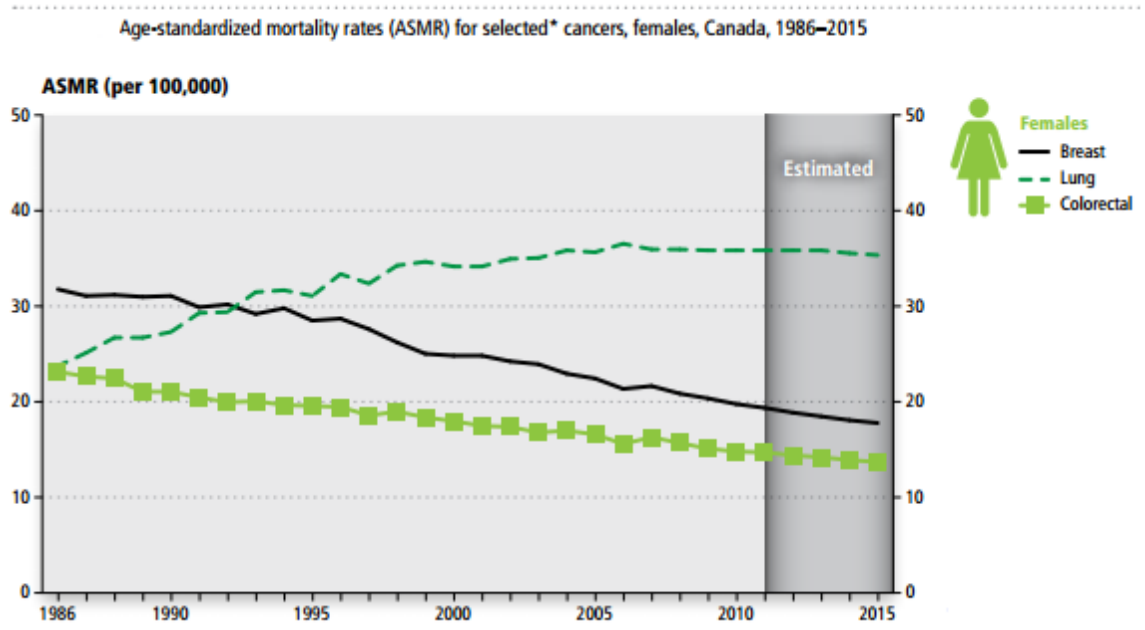

Figure 1.2: **Female mortality rates for selected cancers in Canada, 1986-2015**

(Canadian Cancer Society, p. 42, 2015)

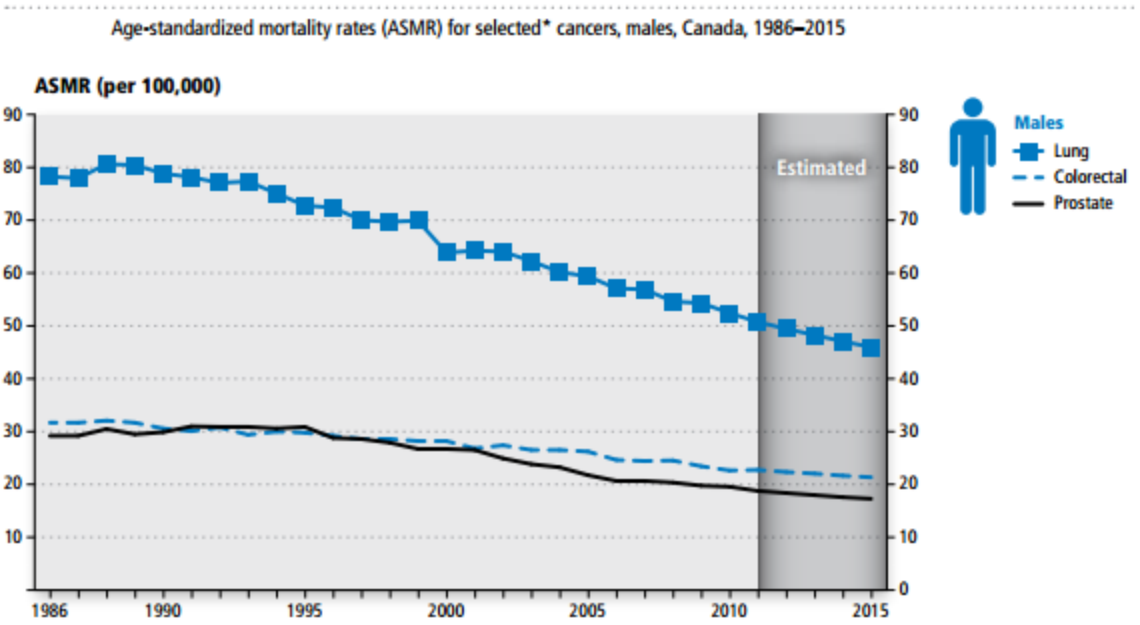

Figure 1.3: **Male mortality rates for selected cancers in Canada, 1986-2015**

(Canadian Cancer Society, p. 41, 2015)

Both figure 1.2 and 1.3 clearly demonstrate that age-standardized mortality rates for colorectal cancers have declined from 1986 to 2015. This is attributed to a combination of factors including: improved screening, risk factor reductions, and enhanced treatments (Canadian Cancer Statistics, 2015).

RECTAL CANCER AS A PROPORTION OF COLRECTAL CANCER

Colorectal cancer can occur anywhere along the colon (right colon, transverse colon, left colon, or sigmoid colon) or rectum (upper rectum, middle rectum or lower rectum). Therefore, rectal cancer is a proportion of all the colorectal cancers. However, in Canadian statistics, these cancers are presented as a conglomerate under colorectal cancers as an inclusive group.

INTRODUCTION OF Mesorectal Excision

Many factors have been studied with respect to optimizing rectal cancer surgery. One large area of interest was introduced in the 1980's, which involved a surgical technique called total mesorectal excision. Heald et al were the first to describe and introduce the operative principle of total mesorectal excision in 1982 (Heald, Husband, and Ryall, 1982). Previously, rectal cancer surgery was performed with manual blunt dissection in the pelvis. "[A] conventional resection… may be characterized as blunt dissection within the pelvis along variable, i.e. non-anatomical planes. The failure to perform a standardized procedure, i.e. anatomical dissection along definable planes, leads to an incomplete resection of the primary rectal tumour along with any regional mesorectal spread" (Havenga, 1999, p. 372). The following illustration demonstrates the correct and incorrect dissection planes of total mesorectal excision.

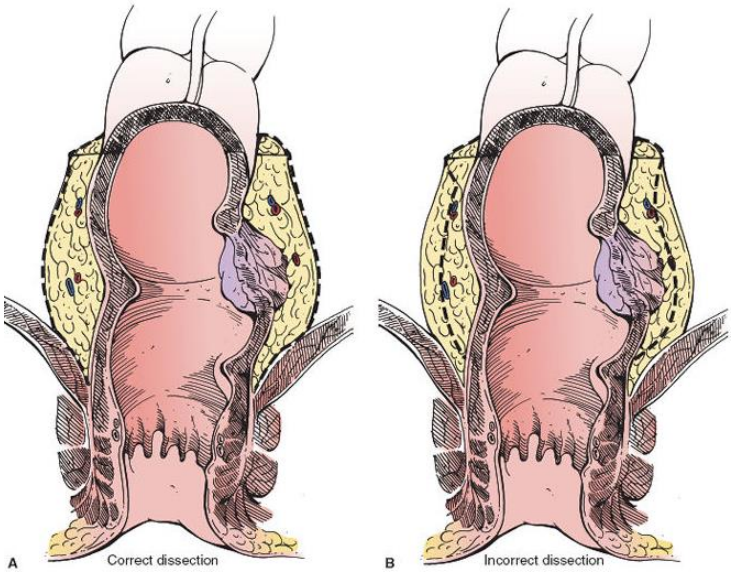

Illustration 1.1: **Mesorectal excision**. A) Correct Dissection, B) Incorrect Dissection (http://www.surgicalcore.org/popup/182828)

According to Parfitt and Driman, who reference Cecil *et al* and Faerden *et al*, this was initially shown by MacFarlane who published follow up data on Heald's practice:

> MacFarlane, who studied with Heald, subsequently published prospective follow-up data based on Heald's practice, the result of which was greatly increased interest in TME technique. The results of these studies showed that TME was a superior surgical modality for the treatment of rectal cancer, as local recurrence rates were reduced from 30-40% without TME to <5% with TME. Subsequent studies have confirmed this and it is now generally accepted that a local recurrence rate of <10% should be expected if proper TME techniques are employed (Parfitt and Driman, 2006, p. 849).

Therefore, the technique to obtain a total mesorectal excision has been widely adopted by all surgeons performing colorectal surgery. "Total mesorectal excision is considered the gold standard for rectal cancer surgery" (Lin, 2011, p. 537).

DEFINITION OF MESORECTAL EXCSION

Various definitions of a total mesorectal excision have been developed. A concise definition of total mesorectal excision is defined by the University of Toronto, Surgical Oncology Manual, as follows: total mesorectal excision involves "excising the rectum en bloc with its blood and lymphatic supply (mesorectum)" (Yasser et al, 2012. p. 216). The following diagram illustrates a lateral view of the total mesorectal excision dissection plane.

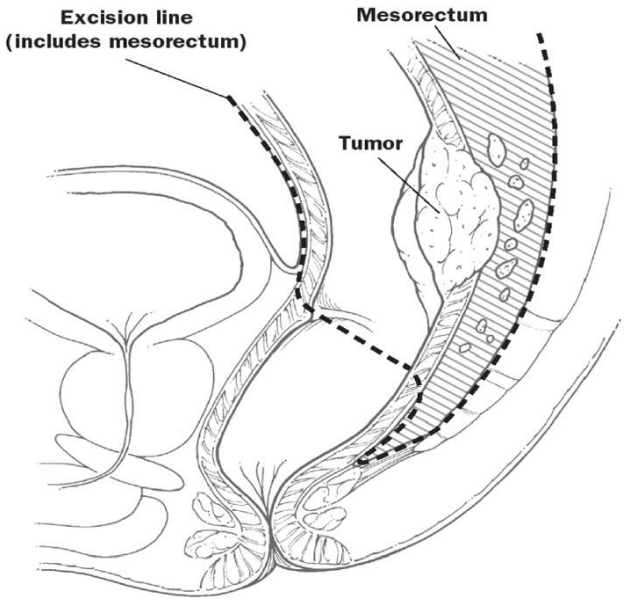

Illustration 1.2: **Mesorectal excision.**

(http://www.cancernetwork.com/cancer-management/colon-rectal-and-anal-cancers/page/0/3)

This illustration depicts the surgical margin when removing a rectal cancer with its encompassing mesorectum, thus resecting the surrounding blood vessels, lymph nodes, lymphatic drainage system, mesentery, and mesorectal fascia. Of note, some sources differentiate total mesorectal excision (TME) from partial mesorectal excision (PME) based on the location of the anatomical resection of the upper, middle, or lower rectum:

> A mesorectal excision can be total (TME) or partial (PME) in extent. The TME refers to complete excision of the mesorectum down to the pelvic floor and is indicated for carcinoma of the middle and lower third of the rectum. In the case of PME, although circumferentially the excision is performed in the same way as TME, the mesorectum is transected at a right angle to the rectal wall at a distance of 5 cm beyond the gross distal edge of the tumour; PME is sufficient for treatment of carcinomas of the upper third of the rectum (Parfitt and Driman, 2006, p. 849).

This definition is used in some, but not all sources. Many sources simply refer to only TME generally and do not mention PME specifically. Therefore, although this distinction is made, for the purposes of this thesis, the term TME has been used for all tumours of the rectum.

One study evaluated showed that a Quality Assessment Instrument could be used to assess Total Mesorectal Excisions. This study was performed by Simunovic et al, in 2014, where they tested the interrater reliability (IRR) of a product analysis tool called the Total Mesorectal Excision- Quality Assessment Instrument (TME-QA). They found that this method of assessment surgical specimens "may provide rapid and relevant feedback to surgeons about their technical performance" (Simunovic et al, 2014, p. 2274). Basically, if there is a standardized way to report TME specimens, with good interrater reliability, then this could be effect for showing "good internal consistency and IRR when the TME-QA is used by pathologists " (Simunovic et al, 2014, p. 2274). This study shows that standard reporting of TME specimens is essential, in order to ensure accuracy of reporting.

SURGICAL TECHNIQUE OF MESORECTAL EXCISION

Optimal surgical resection with meticulous operative technique is imperative to rectal cancer surgery. "The quality of the surgical technique is a key factor in the success of surgical treatment for rectal cancer, both in the prevention of local recurrence and long-term survival" (Washington et al, 2013, p. 16). Obtaining a total mesorectal excision involves a "surgical technique [that] entails precise sharp dissection within the areolar plane outside (lateral to) the visceral mesorectal fascia to remove the rectum. This plane encases the rectum, its mesentery, and all regional lymph nodes and constitutes Waldeyer's fascia" (Washington et al, 2013, p. 16). Thus, "[t]otal mesorectal excision (TME) involves sharp dissection in the plane that separates the visceral mesorectal fascia from the parietal pelvic fascia" (Marr et al, 2005, p. 74). One study, examined 32 cadavers in detail to identify the various fascial planes that encompassed a total mesorectal excision. This study found that, the "autonomic nerves and lateral rectal ligament can be distinguished as the landmark to judge the different planes. The correct surgical plane of the

posterior dissection is conducted between the visceral fascia and parietal fascia, and anterolateral dissection is conducted between the vesicohypogastric fascia and parietal fascia" (Lin et al, 2011, p. 537). Various descriptions of the surgical technique of total mesorectal excision have been described. A thorough description is provided by Heald et al as follows:

> The essence of the surgical technique is the painstaking development under direct visualization of the avascular plane between the mesorectum and the surrounding parietal tissues right down to the distal extremities of the pelvis. The excised specimen thus includes the whole posterior, distal, and lateral mesorectum out to the plane of the inferior hypogastric plexuses, which are carefully preserved. Anteriorly, it includes the intact Denonvilliers fascia and the peritoneal reflection. The characteristic bilobed encapsulated appearance of the intact mesorectum posteriorly and distally reflects the contours of the pelvic floor and the midline anococcygeal raphe. The ideal specimen has a smooth unbroken surface like that of a lipoma. This is achieved by meticulous sharp dissection in the avascular areolar plane surrounding the mesorectum. Finally, great importance is attached to preventing implantation by the use of sterile wash to wash out the rectal stump below a clamp before the anorectum is divided and the pelvis itself, before and after the division. "Heald et al, 1998, p. 895).

This description is very detailed and comprehensive, and thus was included for reference regarding surgical technique of total mesorectal excision.

TYPES OF SURGERIES, TO PERFORM MESORECTAL EXCISION

Surgery has evolved to include several options for the operative management of rectal cancer. "In the recent [two] decades, improvements have been achieved in the outcomes of rectal cancer surgery with the advances in surgical techniques as well as adjuvant therapy. Abdominoperineal resection, the previous gold standard treatment of rectal cancer, has been regarded as unnecessary in most patients with rectal cancer and more patients can now be treated with sphincter-saving surgery" (Law et al, 2004, p. 260). Various surgical approaches, depending on the location of the tumour have been developed for removing the mesorectum with the rectal cancer.

Illustration 1.3: **Types of Rectal Cancer Surgery.**

(https://www.cancersa.org.au/information/a-z-index/surgery-for-bowel-cancer)

Illustration 1.3 depicts the anatomical resection differences between an Anterior Resection (AR), Ultra-Low Anterior Resection (Ultra-LAR), and Abdominoperineal resection (APR). These surgical approaches are clearly defined by the University of Toronto, Surgical Oncology Manual (Yasser et al, 2012), and are described hereafter. An anterior resection (AR) often involves excision of a rectosigmoid or upper rectal cancer, and is defined as, "sharp mesorectal resection down to 5 cm past leading edge" of the tumour. Another surgery, used for resection of upper rectal or middle rectal cancer is the low anterior resection, which is defined as, "a sphincter preserving TME and anastomosis below the peritoneal reflection." If the entire rectum is removed and if an anastomosis is performed, this may be referred to as a proctectomy with coloanal anastomosis (CAA) which may or may not involve J-pouch reconstruction. Lastly, if the entire rectum is removed with an abdominoperineal resection (APR), this is defined as, "TME en bloc with the anus" and this includes a permanent end colostomy (Yasser et al, 2012, p. 216). In addition, the surgeon may elect to perform a stoma to divert the fecal stream and protect a healing anastomosis where the proximal and distal bowel are reconnected. "The creation of a stoma should effectively divert the faecal stream from a healing anastomosis, thereby mitigating the consequences of anastomotic failure" (Peeters, 2005, p. 214). A surgeon may also elect to

perform the surgery using an open technique, or laparoscopic technique. "Laparoscopic TME is a feasible but technically demanding procedure (12% conversion rate)" (Morino, 2003, p. 335). Initial concerns regarding the oncologic safety of laparoscopic surgery have been studied and show equivalency to open procedures. "Laparoscopic TME is feasible and safe. The laparoscopic approach to the surgical treatment of operable rectal cancer does not seem to entail any oncologic disadvantages" (Leroy et al, 2004). In summary, there are many surgical procedures used to operate on rectal cancer and to obtain total mesorectal excisions. These various techniques have been summarized, as they will be recorded amongst the patient data collected within this study.

SURGICAL MARGINS

In addition to obtaining a complete total mesorectal excision for rectal cancer surgeries, it is ideal to obtain negative resection margins. The margins reported in the American Joint Committee on Cancer (AJCC)/ Union for International Cancer Control (UICC) Tumour Node Metastasis (TNM) 7th edition staging system include: closest margin, circumferential (radial) or mesenteric margin (CRM), proximal margin, and distal margin (Washington et al, 2013). Of note, "[t]umour involvement of the proximal bowel margin is unusual, and distal intramural tumour extension more than 2 cm from the primary lesion is uncommon" (Wibe et al, 2002, p327). In contrast to the proximal and distal margins, the CRM remains as a vital prognostic indicator. According the College of American Pathologist guidelines:

> The circumferential (radial) margin represents the adventitial soft tissue margin closest to the deepest penetration of tumor and is created surgically by blunt or sharp dissection of the retroperitoneal or subperitoneal aspect respectively… A positive circumferential (radial) margin in rectal cancer increases the risk of recurrence by 3.5-fold and doubles the risk of death from disease… The circumferential (radial) margin is considered negative if the tumor is more than 1

> mm from the inked nonperitonealized surface but should be recorded as positive if tumor is located 1 mm or less from the nonperitonealized surface because local recurrence rates are similar with clearances of 0 to 1 mm (Washington et al, 2013).

Therefore, the CRM plays a role in overall patient prognosis in addition to TME. This was also demonstrated in a study by Hung-Hsin et al, where they demonstrated that a circumferential resection margin of ≤ 1 mm adversely affected cancer-specific 5-year survival rates (0% vs. 75.8%), local recurrence (15.4% vs. 1.8%) and distant metastasis (61.5% vs. 13.4%), compared to patients with negative CRMs, respectively (Hung-Hsin et al, 2013). Another study showed that "Positive CRM, higher T-stage, and higher N-stage were risk factors for [local recurrence]" (den Dulk et al, 2007, p. 89). Therefore, surgical margins play a role in local recurrence.

LOCAL RECURRENCE

The main argument for performing TME is to decrease local recurrence and increase survival of rectal cancer patients (Carlsen et al 1998, Leroy et al 2004). According to Marsh et al, "[l]ocal recurrence (LR) is defined as recurrent disease in the pelvis, including recurrence at the site of the bowel anastomosis or in the perineal wound" (as cited in Wibe, 2002, p. 859). A major goal in the treatment of rectal cancer is to reduce local recurrence, because the development of a local recurrence has substantial implications for the patient's postoperative course.

> Local recurrence after surgery for rectal cancer is a disaster for the patient. In addition to severe pain, there may be interference with circulation and nerve function of the legs, ureteric obstruction, intestinal obstruction, fistulation, infection and discharge. Cure at this stage is seldom possible and the disease often takes a prolonged and excruciating course. Palliative treatment is not always successful and may in addition have severe side-effects (Arbman et al, 1996, p. 375).

Many factors affect the development of local recurrence. "Positive lymph nodes, N2 disease, lymphatic vascular invasion, and perineural invasion were independent significant risk factors

for local recurrence" (Enker et al, 1997, p. 715). Performing TME is a modifiable risk factor to decrease local recurrence and increase survival of rectal cancer patients.

Previous research has been done on the prognostic significance associated with the Total Mesorectal Excision. Martling et. al. did a study, in 2004, which they analyzed "the prognostic value of surgeons' and pathologists' assessments of tumour clearance in patients with primary rectal cancer." In this study, 1550 patients were studied prospectively, where both the surgeons and pathologist reported if the tumour clearance was 'complete', 'uncertain', or 'incomplete.' Of note, in "patients assessed as having a complete surgical clearance, tumour recurrence developed in 33.3 per cent. For patients with an uncertain or incomplete clearance the recurrence rate was 59.5 and 61 per cent respectively ($P < 0.001$)". The authors therefore concluded that, "[a]ssessments of tumour clearance were of strong prognostic value in relation to outcome. When the surgeon or pathologist was uncertain, or there was disagreement about the completeness of clearance, the risk of recurrence was similar to that among patients in whom an incomplete resection had been performed" ((Martling et al, 2004, p. 1040). This study shows that the pathologist's and the surgeon's prediction of TME results has an important implication in prognosis for the patient.

PHYSIOLOGICAL OUTCOMES AFTER TME

Not only is total mesorectal excision imperative for oncologic outcomes, it is also essential for physiologic outcomes, which are impacted by surgery and other factors like radiation therapy. Specifically, autonomic nerve preservation (ANP) during total mesorectal excision has been described as an integral part of rectal cancer surgery to preserve sexual function (Enker et al, 1997). "Preservation of the intact superior and inferior hypogastric

plexuses and hypogastric nerves safeguards sexual and bladder function" (Brown et al, 2004, p. 432). Of note, the addition of radiotherapy to TME adds additional morbidity. "Although preoperative short-term radiotherapy for rectal cancer results in increased local control, there is more long-term bowel dysfunction in irradiated patients than in patients who undergo TME alone" (Peeters et al, 2005, p. 6199). Therefore, autonomic nerve preservation during TME is important because the addition of radiation can also impact nerve function.

COMBINED MODALITY, MULTIDISCIPLINARY TREATMENT

Initially, surgery alone was found to be insufficient in the treatment of rectal cancer. "The standard surgical approaches of abdominoperineal (AP[R]) resection or anterior resection (AR) have produced disappointing results, both in local control and in overall survival. This has prompted the development of adjuvant strategies using radiotherapy, chemotherapy, or both to improve outcomes" (Heald et al, 1998, p. 894). Research advances in the last few decades have found that surgical management of rectal cancer is optimized with a multidisciplinary approach combing surgery, chemotherapy, and radiotherapy. Many studies have found that radiotherapy has a beneficial effect in reducing local recurrence. One study by Kapiteijn examined 1748 patients who were randomly assigned to macroscopically complete local resection surgery, with or without radiotherapy. "The rate of local recurrence at two years was 2.4 percent in the radiotherapy-plus-surgery group and 8.2 percent in the surgery-only group ($P < 0.001$)." (Kapiteijn et al, 2001, 638). Therefore, the authors concluded that, "[s]hort-term preoperative radiotherapy reduces the risk of local recurrence in patients with rectal cancer who undergo a standardized total mesorectal excision (Kapiteijn et al, 2001, 638). Additionally, it has been shown in the literature that chemoradiotherapy (CRT) in addition to TME aids in obtaining negative resection margins. "Capecitabine/oxaliplatin before synchronous CRT and TME results

in substantial tumor regression, rapid systematic response, and achievement of RO resection" (Chau et al, 2006, p. 668). Therefore, improving rectal cancer outcomes is multifaceted as it involved multidisciplinary treatment.

RESEARCH ADVANCES

Ideally, the treatment of rectal cancer is optimized. In a paper from 1999, there were many obstacles standing in the way of optimizing rectal cancer treatment. At that time, the authors noted, "Quality control, training and the education of surgeons in practice, as well as standardization of other involved disciplines, i.e. pathological evaluation, remain the major problems to be addressed in the future" (Havenga et al, 1999, p. 373). Major strides in rectal cancer surgery, pathology, and treatment have been made since 1999. Ideally, we will continue to advance with ongoing research in the rectal cancer field.

RATIONALE AND OBJECTIVES

As mentioned, rectal cancer is life threatening condition that impacts patients within the province of Saskatchewan. Numerous previous studies have shown that the local recurrence and overall survival is impacted by the surgical excision of rectal cancer. The standard treatment, when resecting rectal cancers with curative intent, is to obtain a total mesorectal excision in order to reduce local recurrence and improve overall survival.

Currently, rectal cancer surgery within the province of Saskatchewan has remained largely unstudied. We are interested in investigating the surgeon's perception of completeness of excision after performing each rectal cancer surgery and correlating this with the patient's pathology data. The research question in this study aims to identify how accurate a surgeon's perception is in predicting the results of mesorectal excisions as complete, nearly complete or incomplete. Furthermore, we would like to ask surgeons to identify factors that affect their ability to achieve a total mesorectal excision. Surgeons can identify factors that made the dissection of the TME more difficult or less difficult in an open ended fashion. The pathology specimen will then be analyzed by the pathologist and will be reported as complete, nearly complete, or incomplete.

Statistical analysis will then be performed to assess the accuracy of a surgeon's prediction of the TME results using Kappa stastics. This will identify how accurate a surgeon's perception is, with respect to predicting the Total Meosrectal Excision as incomplete, nearly complete, or complete.

MATERIALS AND METHODS

The study design involves a chart review to collect patient data and a survey to ask surgeons questions regarding a patient's surgery. This study was developed prospectively, largely to evaluate a surgeon's perception of rectal cancer surgeries with respect to Total Mesorectal Excision (TME). The benefits of performing TME surgery well known in the literature. However, asking the surgeon to predict their own pathology results required prospective data collection and analysis prior to release of pathology data.

There are many possible definitions of the rectum. For the purposes of this study, the anatomical definition of the rectum to be used within the study had to be defined. The definition selected for the purposes of this study was developed by the College of American Pathologists, from the 2013 guidelines (Washington et al, 2013). This definition is as follows:

Definition of Rectal cancers: based on CAP (College of American Pathologists) Guidelines (2013):

The rectum, with approximate dimensions measuring 12 cm long from the anal verge, constitutes three anatomical segments:

-Upper third: covered by peritoneum on anterior and lateral surfaces

-Middle third: covered by peritoneum only on anterior surface

-Lower third: has no peritoneal covering

The transition from sigmoid to rectum is marked by the fusion of the tenia coli of the sigmoid to form the circumferential longitudinal muscle of the rectal wall approximately 12 to 15 cm from the dentate line. The rectum is defined clinically as the distal large intestine commencing

opposite the sacral promontory and ending at the anorectal ring, which corresponds to the proximal border of the puborectalis muscle palpable on digital rectal examination. When measuring below with a rigid sigmoidoscope, it extends 16 cm from the anal verge.

This definition of the rectum clearly differentiates the upper, middle, and lower rectum. Furthermore, it includes different anatomical characteristics including peritoneum, tenia coli, dentate line, sacral promontory, anorectal ring and puborectalis muscle; all of which are important in delineating the rectum both surgically and pathologically. Lastly, this definition includes the definition of the rectum from the endoscopic perspective, with using the rigid sigmoidoscope.

Types of Total Mesorectal Excision (TME) had to be defined for the purposes of this study as well. Mesorectal excisions can be classified as incomplete, nearly complete and complete.

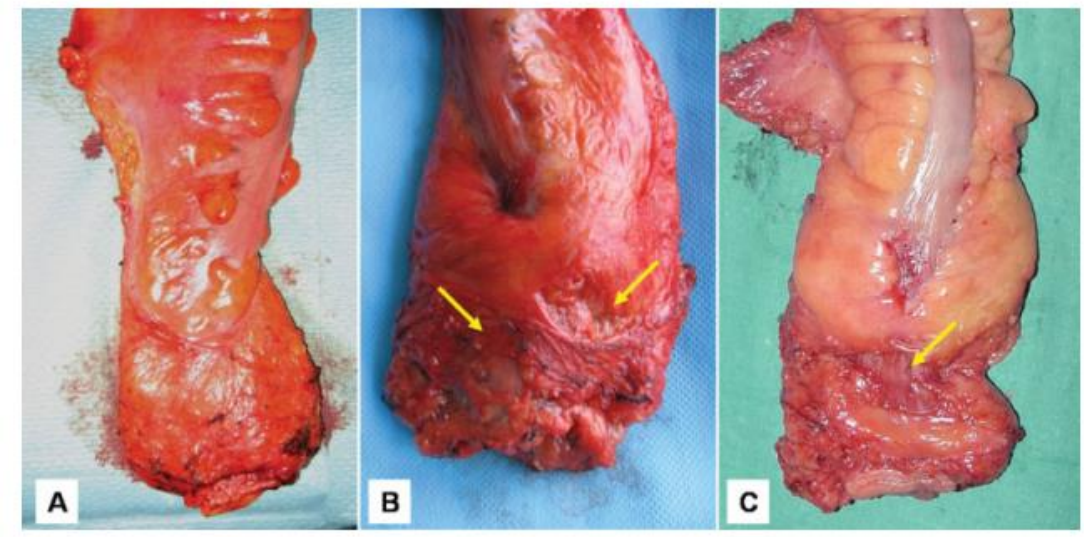

Illustration 1.4: **Types of Mesorectal Excision:** A) Complete B) Nearly complete C) Incomplete

(http://onlinelibrary.wiley.com/doi/10.1002/cncr.24387/pdf)

Of note, the anterior and posterior view of a complete mesorectum can be differentiated grossly based on the appearance. The normal anatomical landmark of a midline cleft, also known as a "rectal buttocks," is seen on the posterior aspect of the mesorectum and is characteristic of a complete mesorectal excision. This is depicted in the following illustration provided by Parfitt and Driman (Parfitt & Driman, p. 851, 2006):

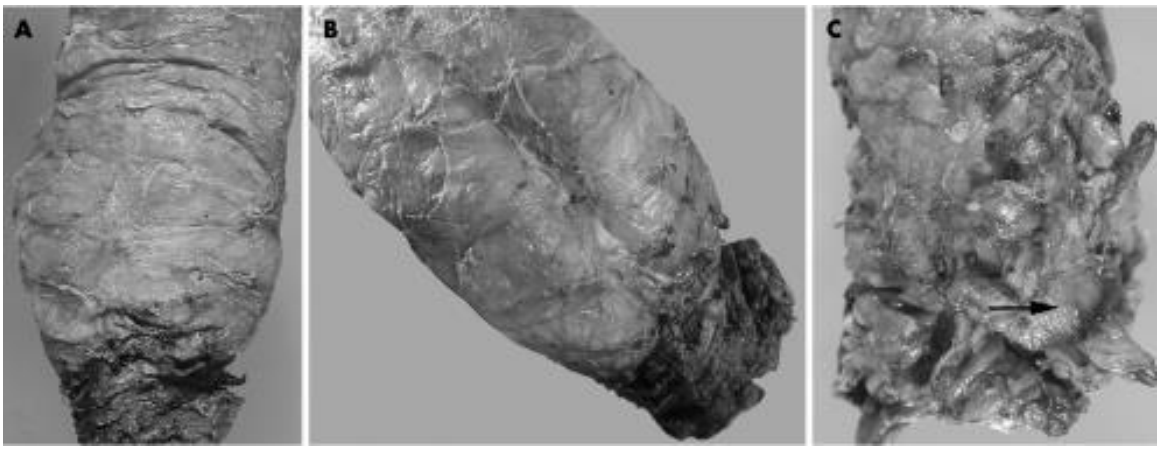

Illustration 1.5: **Types of Mesorectal Excision:**
A) Complete – Anterior view B) Complete – Posterior view C) Incomplete (the arrow points to a deep defect exposing the muscularis propria)
(http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1994509/#!po=35.1852)

Each of these types of mesorectal excision is classified based on their gross macroscopic pathology, examined in the pathology department. The College of American Pathologists clearly defined what defines each type of mesorectal excision, as follows (Washington et al, 2013):

Mesorectal Excision:

Incomplete

-Little bulk to the mesorectum

-Defects in the mesorectum down to the muscularis propria

-After transverse sectioning, the circumferential margin appears very irregular

Nearly Complete

-Moderate bulk to the mesorectum

-Irregularity of the mesorectal surface with defects greater than 5 mm, but none extending to the muscularis propria

-No areas of visibility of the muscularis propria except at the insertion site of the levator ani muscles

Complete

-Intact bulky mesorectum with a smooth surface

-Only minor irregularities of the mesorectal surface

-No surface defects greater than 5 mm in depth

Each rectal cancer in Saskatchewan is reported pathologically in a standard reporting format used by all pathologists. This is the current total mesorectal excision definition used for the American Joint Committee on Cancer (AJCC)/ Union for International Cancer Control (UICC) Tumour Node Metastasis (TNM) 7th edition staging system used in current pathology reporting in Saskatchewan.

The study design initially involved a one-year prospective research project, which was subsequently extended to include a second year of data collection to maximize patient accrual.

This study was approved by the Biomedical Research Ethics Review Board for both the University of Saskatchewan and the University of Regina. Ethics approval was granted in August of 2014 and subsequent data collection was initiated. The ethics was renewed in August 2015 to include a second period of data collection over another year.

The goal of this study was to include several hospitals within Saskatchewan to maximize surgeon and patient data accrual and to include patients from several hospitals in Saskatchewan. Furthermore, this broad-based approach was used to attempt to represent the majority of rectal cancer patients treated in Saskatchewan. A total of four hospital sites were included in the study within different health regions. Each hospital site was de-identified and kept confidential within the study. Hospital site names were coded for the purposes of data collection and data analysis.

Two surveys were issued to each participating surgeon. The first survey was an intake survey of each participating surgeon to be completed once at the beginning of the study. The second survey was a patient related survey. This second survey was to be completed by the performing surgeon each time a rectal cancer is resected.

Informed consent by participating surgeons was required for this study. General surgeons were identified amongst four hospitals within Saskatchewan by their central departmental offices. Surgeons were subsequently invited to participate in the study by email invitation. There were no exclusion criteria for the surgeon's participation. Surgeons, who agreed to participate in the study, subsequently completed an online survey. This survey was provided through the Fluid Surveys tool provided by the University of Saskatchewan. Consent was obtained by completion

of reading an informed consent form within the survey. Each surgeon was informed of the potential risks and potential benefits of the study. These risks and benefits were reviewed and approved by the research ethics board. Risks and benefits identified by REB:

Potential Risks:

-All reasonable steps will be made to ensure patient privacy and is protected within this study and patient confidentiality is maintained.

-All surgeons will be de-identified and their identity will be confidential in the study results.

-Surgeons will have access to their own results and to the study results after study completion.

Potential Benefits:

-Identification of the number of rectal cancer patients treated in Saskatchewan

-Identification of the number of Total Mesorectal Excisions performed

-Identification of Surgeon's perceptions of Rectal Cancer Surgeries.

-May develop areas of future study - e.g. questions may arise from research regarding future research in Rectal Cancer.

All of these potential risks and benefits were clearly stated on the consent form. Furthermore, each surgeon was informed that the results of the study were to be kept confidential. Surgeons were informed, patient and surgeon data would be kept confidential, each surgeon's data was to be de-identified, and no surgeon's name would be published or revealed in any study publications. Surgeons provided consent by stating they agree to participate in the study and they would subsequently indicate this by pressing a button within the online survey. Each surgeon was informed that they had the right to withdrawal from the study at any time.

Each surgeon was asked demographic information (name, email, hospital of practice, years of practice), and training background (year completed medical school, year completed surgical training, and if any fellowship or subspecialty training). Each surgeon was also given the opportunity to request results of the study once they were available. For the purposes of the study data collection, each surgeon's name de-identified and assigned a surgeon identification code number, to code each surgeon's name on the survey and within the data analysis. Once surgeons enrolled in the study, data collection regarding rectal cancer surgeries commenced.

Data collection involved two phases of collection. The first phase of data collection involved obtaining patient-specific surgery data from the individual participating surgeons. The second phase of data collection involved collecting patient data from a chart review and pathology report review.

Consent was waived for patient participation within the study. Patients were identified for inclusion within the study from operative slates provided at each hospital site. It was not possible to identify or contact patients preoperatively. Often, contact information is obtained for patients on the day of admission of surgery. It was agreed upon, along with the research ethics review board, that obtaining consent for data collection from patients post-operatively may induce anxiety regarding TME results and pending pathology reports. Therefore, this was treated like a quality improvement initiative where consent is not required to analyze patient data. Patient data was to be kept confidential. Each patient was given a study identification code for data collection and analysis. The only patient data collected on a study code form included the patient's medical record number (MRN) for hospital chart access and the patient's personal health number (PHN) for pathology data access. Data collection did not include the patient's name or date of birth as this was not essential for patient identification for the purposes of this study.

Patient inclusion criteria were: adults, age greater than or equal to 18 years of age, male and female patients, and patients who underwent rectal cancer resection surgery. All of these patients must have been treated with surgical resection at one of the four hospital sites included within the study. Patient exclusion criteria were: children less than 18 years old and those with pathology specimens that may have been sent out of province for analysis where data is not available.

Once a rectal cancer patient was identified on the operative slate of a consenting surgeon, patient MRN and PHN was recorded on the study patient identification code form. Once surgery was completed, the operative report was reviewed to confirm the patient was treated with resection for a rectal cancer. A survey, Patient Related Questionnaire of Participating Surgeons, was then sent to the surgeon regarding the patient's surgery. This survey was sent electronically via email using the University of Saskatchewan Fluid Surveys tool. The first page of the survey form included pre-entered information on the month, date, year, procedure performed, and surgeon identification code. Surgeons were sent the survey shortly after the surgical procedure, ideally within 24-48 hours of the surgery. Surgeons received an email requesting completion of the survey. Each email also contained the pre-entered information on the month, date, year, procedure performed, and surgeon identification code. The email also had direct website link to the specific Fluid Survey created for each surgical patient. No identifying patient information was included on the email or the online survey. In the event that more than one surgical procedure for rectal cancer was performed in one day, an optional entry on the first page of the survey included the time of the procedure, so that surgeon could differentiate two or more possible patients receiving rectal cancer surgeries on the same day. As discussed with the research ethics board, if a surgeon could not remember which patient was operated on, the plan

was for the research personnel to contact the surgeon by phone call to provide patient identification so that the surgeon could complete the appropriate survey. However, this contingency plan was not necessary over the course of the study, as surgeons were able to identify from the month, day, year, and procedure performed, which patient a survey was referring to. If a surgeon was not able to complete a survey, a reminder email was sent to the surgeon within 72 hours of the initial survey invitation.

The study was designed to have the surgeon to complete the patient-specific survey prior to the release of pathology data. This would allow the surgeon to predict the pathology data prior to its release. The pathology report was generally released within 2-4 weeks post operatively.

The Patient Related Questionnaire of Participating Surgeons asks questions about date of surgical procedure performed, confirmation that the surgery was performed for a rectal tumour, and the surgeon's prediction of the mesorectal excision (complete, nearly complete, or incomplete). Each surgeon was asked if the surgery was indeed performed for a rectal cancer (yes/no). Furthermore, each surgeon was asked if the surgery was performed with curative intent (yes/no). The surgeon was also asked to list possible factors that made the mesorectal excision more difficult or less difficult.

To minimize the work load on the surgeon, the remaining patient data was collected by the research personnel. Patient data was accessed online from hospital based computers utilizing the Sunrise Clinical Manager electronic patient record. The patient data collection forms recorded information on sex, age, medical history, surgical history, body mass index if available, preoperative chemotherapy, preoperative radiotherapy, surgery performed, complications, estimated blood loss, preoperative pathology, and postoperative pathology. All of the rectal

cancer specimens were processed by the pathology departments as per standard practices. Pathology information collected includes tumour characteristics (type, location, size, and stage), TME classification, margin status, histologic characteristics (type, grade), microscopic tumour extension, lymphovascular invasion, perineural invasion, and type of polyp in which the rectal cancer arose. Additionally, data was collected on ancillary studies performed by the pathology department (special stains, microsatellite instability, immunohistochemistry for mismatch repair proteins, and mutational analysis). Also, if the patient received neoadjuvant chemotherapy or radiation prior to surgery, it was documented if a treatment effect was identified pathologically.

RESULTS

Surgeons at four hospital sites within Saskatchewan were invited to participate in this study. Approximately 25-30 surgeons were invited to participate. The goal number of surgeons to participate in the study was 5-10 surgeons, as a proportion of these surgeons do not practice rectal cancer surgeries within their general surgery practice. A total of 8 surgeons consented to participate and enrolled in the study across the province of Saskatchewan. Each surgeon was enrolled during the entire study period. There was no withdrawal of consent to participate in the study submitted by any of the participating surgeons.

Rectal cancer patients were enrolled starting when ethics approval was obtained on August 29, 2014. Patient enrolment continued into a second year of the study while ethics approval was extended until August 2016. Actual data collection continued until April 2016 and then ceased once research study goals of 10-15 enrolled patients were met.

Surgical slates were examined among the hospital sites of the participating surgeons. When a rectal cancer resection surgery was identified on the operative slates, operative records were reviewed to ensure surgical resection was indeed performed for a rectal cancer. Subsequently, consenting surgeons were sent surveys regarding their prediction of the Total Mesorectal Excision pathology results.

A total of 16 patients were enrolled in the study. Data was collected on each individual patient's characteristics. The surgical procedure was recorded. Each surgeon was asked to confirm if the procedure was performed for a rectal cancer and if the procedure was performed with curative intent. All the surgeons stated that each patient was indeed diagnosed with a rectal cancer (100%, 16/16 patients). Furthermore, all the surgeons stated that each patient was treated

with a curative intent, and therefore no palliative resection procedures were performed (100%, 16/16 patients). The following table summarizes all the procedures performed on the rectal cancer patients in this study.

	Procedure Performed	Procedure Performed for Rectal Cancer	Procedure Performed with Curative Intent
1	APR, Posterior Vaginectomy	Yes	Yes
2	Laparoscopic LAR with diverting ileostomy	Yes	Yes
3	Laparotomy, LAR, Bilateral ureterolysis, Loop ileostomy	Yes	Yes
4	Open LAR	Yes	Yes
5	Exploratory Laparotomy, Adhesionolysis, APR	Yes	Yes
6	Laparoscopic assisted APR	Yes	Yes
7	Open APR	Yes	Yes
8	Laparoscopic converted to open APR	Yes	Yes
9	Laparoscopic converted to open LAR with diverting loop ileostomy	Yes	Yes
10	Open APR	Yes	Yes
11	Laparoscopic assister LAR with coloanal anastomosis and Loop Ileostomy	Yes	Yes
12	Laparoscopic assisted LAR and loop ileostomy	Yes	Yes
13	LAR, End Colostomy, Right pelvic sidewall lymph node dissection	Yes	Yes
14	Pelvic exenteration, LAR, cystoprostatectomy, ileal conduit, colostomy	Yes	Yes
15	Laparoscopic assisted LAR, loop ileostomy, rigid sigmoidoscopy	Yes	Yes
16	APR	Yes	Yes

Table 1.3: **Procedures performed for each enrolled patient in the study with confirmation from surgeons performing procedures that the procedures were performed for rectal cancers with curative intent.** (Blue = APR, Light grey = LAR)

Pathology results were examined and collected for each enrolled patient. Data analysis of patient pathology data quantified the number of complete, nearly complete and incomplete total mesorectal excisions performed by each enrolled surgeon. The surgeon's predicted TME result was compared to the actual TME result reported in the pathology report. Each patient's result was analyzed to see if the predicted result correlated with the actual reported result.

	MESORECTAL EXCISION: Complete, Nearly Complete, Incomplete	
	Surgeons Prediction of Mesorectal Excision	**Pathologic Mesorectal Excision**
1	Nearly Complete	Nearly Complete
2	Nearly Complete	Complete
3	Complete	Complete
4	Complete	Complete
5	Nearly Complete	Complete
6	Complete	Nearly Complete
7	Complete	Complete
8	Nearly Complete	Complete
9	Complete	Complete
10	Complete	Complete
11	Complete	Complete
12	Nearly Complete	Incomplete
13	Complete	Nearly Complete
14	Complete	Complete
15	Complete	Complete
16	Complete	Incomplete

Table 1.4: **Surgeon prediction of mesorectal excision versus pathological classification of mesorectal excision.** (shaded = consistent result, unshaded = inconsistent result)

A total of 9/16 surgeon's predictions were consistent with the pathological results of classifications of mesorectal excisions. The surgeon's prediction differed from the pathology report in 7/16 cases.

The Clinical Research Unit (CRU) at the University of Saskatchewan, under the supervision of Dr. June Lim, assisted with the data analysis. Their assistance was used to determine if there is a statistical correlation between the surgeon's perception of completeness of mesorectal excision and the pathology data obtained from the study. As previously discussed with the CLR, this statistical analysis used Kappa statistics to analyze if there was statistical agreement between the categorical data. In essence, this allowed the study to evaluate how accurate surgeons are in predicting TME completeness in comparison to actual pathology data obtained for each patient.

Each surgeon was asked in each patient-specific survey if there were any factors that made the total mesorectal excision more or less difficult to perform intraoperatively. This question was intentionally left open-ended to allow surgeons to decipher their own reasons for intraoperative factors that may have affected the dissection. The data was then further evaluated to assess if common factors were identified by the surgeons that made TME less or more difficult to attain.

	Factors that made Mesorectal Excision More Difficult	**Factors that made Mesorectal Excision Less Difficult**
1	Previous hysterectomy with some adhesions requiring partial vaginectomy, Anterior Tumour especially considering previous surgery, Very friable fatty mesentery	None Listed
2	Anatomical - bulky mesorectum, Narrow male pelvis	None Listed
3	Post-radiation fibrosis (radiation was >12 weeks before surgery), Bulky tumour as patient was unable to complete chemoradiation	None Listed
4	Location of lesion at 7 cm, Uterus still present	Female pelvis

5	Inflammatory state continued after a significant adhesionolysis two nights previously	None Listed
6	Patient obesity with BMI 38	None Listed
7	None Listed	Lack of neoadjuvant chemoradiation, Wide pelvis, Female
8	Body habitus - fat male with narrow pelvis	None Listed
9	Body habitus - narrow male pelvis	None Listed
10	Male, overweight body habitus, post-radiation	None Listed
11	None Listed	None Listed
12	None Listed	None Listed
13	Bulky tumour	None Listed
14	Locally advanced tumour	None Listed
15	None Listed	None Listed
16	Patient body habitus (narrow male pelvis, obese)	None Listed

Table 1.5: **Factors listed by the surgeon, for each individual case, that made mesorectal excision more or less difficult.**

Each surgeon's response to the question regarding factors that made the mesorectal excision more or less difficult was answered in an open-ended fashion. This allowed surgeons to answer in a non-biased manner, which factors they perceived affected their ability to obtain a complete mesorectal excision.

The data was analyzed using kappa agreement calculation. The calculation was performed using a cross tabulation of surgeon prediction of TME as incomplete, nearly complete or complete versus pathology results of incomplete, nearly complete, or complete. There were a total of 16 patients and 16 respective operative cases/specimens analyzed. This data is presented in the following table.

Kappa agreement calculation

Surgeon prediction * Pathology Cross tabulation

Count

		Pathology			
		Nearly complete	Complete	Incomplete	Total
Surgeon prediction	Nearly complete	1	3	1	5
	Complete	2	8	1	11
Total		3	11	2	16

Table: 1.6: **Cross Tabulation of Surgeon Prediction vs. Pathology**

Once the cross tabulation was performed, the data was further analyzed using the kappa agreement calculation. This is presented in the following table.

Symmetric Measures

		Value	Asymptotic Standardized Error[a]	Approximate T[b]	Approximate Significance
Measure of Agreement	Kappa	.067	.196	.341	.733
N of Valid Cases		16			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Table: 1.7: **Kappa Agreement Calculation of Surgeon Prediction vs. Pathology**

This data demonstrated a kappa value of 0.067 which corresponds with an approximate significance value of 0.733. This suggests poor and non-significant correlation between surgeon prediction of completeness of total mesorectal excision and pathology result as incomplete, nearly complete, or complete.

DISCUSSION

A surgeon's perception of Total Mesorectal Excision has been largely unstudied to date. Surgeons often rely on many intraoperative cues to guide their surgical dissection. Various intraoperative findings including anatomical landmarks, tactile sensations, evidence of metastatic disease, and tumour factors guide intraoperative management.

This study pointedly asks surgeons which factors may have made it more or less difficult to obtain a TME. This question was intentionally left open ended so surgeons could list various factors which may have affected the TME resection in patient-specific scenarios. Various answers were obtained regarding these factors. Common reasons listed that made the mesorectal excision more difficult included: male pelvis, large body habitus, adhesions from previous surgeries, bulky tumour and post-radiation fibrosis. Common reasons listed that made the mesorectal excision less difficult included: female pelvis. In most cases, surgeons did not list any factors that made the mesorectal excision less difficult.

Furthermore, we asked surgeons to predict their own patient's TME results. We did hypothesize that surgeons would be relative accurate in predicting the TME results. Of note, there is absolutely no requirement for a surgeon to do this accurately. However, we expected that based on intraoperative findings and experience, each surgeon would be able to do this quite accurately.

A total of 16 operative cases and 16 specimens were analyzed for this study. Of all these cases, the surgeon correctly predicted the pathology results in 9 out of 16 cases, or 56.25% of the time. Data analysis was performed using a kappa agreement calculation. The calculation was performed using a cross tabulation of surgeon prediction of TME as nearly complete or complete

versus pathology results of nearly complete, complete or incomplete. The data demonstrated a kappa value of 0.067. Basically, the kappa value is a measure of interobserver agreement between the pathologist and the surgeon. “Precision, as it pertains to agreement between observers (interobserver agreement), is often reported as a kappa statistic.” (Viera et al, 2005, p. 360). Values can range from negative one to positive one. A value less than 0 represents an agreement that occurs less than chance. A value of 0 represents a poor agreement. A value of 0.99 represents almost perfect agreement (Viera et al, 2005, p. 360). The kappa value in this study of 0.067, corresponds with a significance value of 0.733, suggesting poor and non-significant correlation between surgeon prediction of completeness of total mesorectal excision and pathology result.

Various limitations of this research study were identified during this project. One limitation of this study was that the pathology process of reporting specimens was not altered. Each pathology report was reported according to the College of American Pathologist guidelines that are currently used across the pathology departments. However, this study did not require that a specimen was read any differently than it otherwise would be. For example, some studies mandate that the specimen is double read by a second pathologist. Another example would be that a central review process could be set up to review the specimens in a standard centralized format for all patients in the study. This was not done, as our current health care resources for pathology processing would not allow for any further patholological processing as a result of this study to be carried out.

It is possible, that a higher number of patients would be required to produce a significant result between surgeon prediction of TME and pathology results. However, is also possible that a surgeon’s perception may not allow them to accurately predict the TME pathology results.

Therefore, it is imperative to have an outside source, i.e. the pathologist, exam the specimen and determine if the TME is incomplete, nearly complete or complete. This objective assessment allows classification of the TME specimen.

It is also possible, that surgeons are simply inaccurate in predicting the TME specimens. The surgeon is obligated to remove the cancer, whilst upholding the surgical principles of oncologic removal. However, there is no obligation of the surgeon to accurately predict the pathology result. It is possible, that intraoperative cues, such as tactile sensation, visual inspection, palpation, and other factors, are not sufficient to allow the surgeon to accurately predict the pathology results. This study emphasizes the need for an outside, objective pathologist to analyze the specimen and assess the total mesorectal excision.

CONCLUSION

In conclusion, rectal cancer remains a disease requiring multidisciplinary treatment with various combinations of chemotherapy, radiation, and surgery. Surgery with total mesorectal excision remains an integral part of treatment to ensure patients can be potentially cured with decreased local recurrence and improved overall survival.

Surgical practices in Saskatchewan regarding Total Mesorectal Excision have remained largely unstudied until recently. Our goal of this study was to evaluate a surgeon's perception of Total Mesorectal Excision after each rectal cancer surgery was performed. All data was collected prior to pathology results being available. Therefore, each surgeon was asked without knowing actual pathology results if predicted the perceived Total Mesorectal Excision to be complete, nearly complete or incomplete. Most surgeons reported the TME as complete or nearly complete.

In addition, each surgeon was asked which operative factors may have made the dissection more or less difficult and thus could have influenced obtaining a Total Mesorectal Excision. Various answers were obtained regarding these factors. Common reasons listed that made the mesorectal excision more difficult included: male pelvis, large body habitus, adhesions from previous surgeries, bulky tumour and post-radiation fibrosis. Common reasons listed that made the mesorectal excision less difficult included: female pelvis.

The data from this study included analysis on 16 enrolled patients. This demonstrated a kappa value of 0.067 which corresponds with an approximate significance value of 0.733, suggesting poor and non-significant correlation between surgeon prediction of completeness of total mesorectal excision and pathology result.

The element of knowledge translation and how this information will be passed on further is an important element of this research project. Each surgeon, who has requested their own results, will be provided with their own results and the final results of this research study. Furthermore, this project will be submitted for presentation at the University of Saskatchewan, Division of Surgery, Resident Research Day in 2017. Other venues to disseminate this knowledge will be applied for, in order to disseminate the results of this study in both Saskatoon and Regina, Saskatchewan. Furthermore, this data will be published in thesis format, and then will be submitted for publication in primary journal literature.

There are several areas of possible future research. As this study did not examine all hospital sites within Saskatchewan, there is more information to be gained regarding the total number of rectal cancer surgeries performed within Saskatchewan per year. Furthermore, each surgeon had to consent to participate within this study. Therefore, there is unattained data from surgeons who did not consent for participation in this study. Further research could also be done in this area to see if higher numbers of enrolled patients could produce a significant result between surgeon's prediction of TME and pathology results.

It is also possible, that surgeons are simply inaccurate in predicting the TME specimens. The surgeon is obligated to remove the cancer, whilst upholding the surgical principles of oncologic removal. However, there is no obligation of the surgeon to accurately predict the pathology result. It is possible, that intraoperative cues, such as tactile sensation, visual inspection, palpation, and other factors, are not sufficient to allow the surgeon to accurately predict the pathology results. This study emphasizes the need for an outside, objective pathologist to analyze the specimen and assess the total mesorectal excision.

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Total mesorectal excision illustration. Image retrieved from:

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APPENDICES

-Consent Form

- Intake Questionnaire of Participating Surgeons

- Patient-related Questionnaire of Participating Surgeons

- Patient Data Collection Form

-REB Application

PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: **Surgical Practices in Saskatchewan: Researching a Surgeon's Perception of Total Mesorectal Excision**

Principal Investigator:

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INTRODUCTION

You are invited to take part in this research study because you are a surgeon within the province of Saskatchewan who may be performing rectal cancer surgeries.

Your participation is voluntary. It is up to you to decide whether or not you wish to take part in this study. If you decide to participate, you are still free to withdraw at any time and without giving any reasons for your decision. Please take time to read the following information carefully. You can ask the study physicians to explain any information that you do not clearly understand. You may ask questions as you need.

WHO IS CONDUCTING THE STUDY?

This study is being conducted within the Clinical Investigator Program at the University of Saskatchewan by Dr. Gary Groot (General Surgeon, Principal Investigator) and Dr. Julie Kickbush (General Surgery Resident, Health Sciences Masters Student).

This project is sponsored by the Division of General Surgery within the Clinical Investigator Program at the University of Saskatchewan. Neither the institution, nor any of the investigators or staff, will receive any direct financial benefit from conducting the study.

WHY IS THIS STUDY BEING DONE?
Rectal cancer is life threatening condition that impacts patients within the province of Saskatchewan. Numerous previous studies have shown that the local recurrence and overall survival is impacted by the surgical excision of rectal cancer. The standard treatment, when resecting rectal cancers with curative intent, is to obtain a total mesorectal excision in order to reduce local recurrence and improve overall survival.

Currently, there is no pooled surgical and pathology data on rectal cancer surgeries within the province of Saskatchewan. Furthermore, research has not been conducted on perceptual factors of a surgeon that may affect rectal cancer excisions.

We are interested in investigating how many rectal cancer surgeries are being performed, how many surgeons are performing rectal cancer surgeries, and how many total mesorectal excisions are being performed. We are also interested in investigating the surgeon's perception of completeness of excision after performing each rectal cancer surgery and correlating this with the patient's pathology data.

WHO CAN PARTICIPATE IN THE STUDY?
You are invited to participate in this study if you are surgeon within the province of Saskatchewan who is performing rectal cancer surgeries at Royal University Hospital (Saskatoon, SK), St. Paul's Hospital (Saskatoon, SK), Regina General Hospital (Regina, SK), and/or Pasqua Hospital (Regina, SK).

WHAT DOES THE STUDY INVOLVE?
This study is being done prospectively over one year (March 2014 - March 2015) to understand the rectal cancer surgeries currently done within the province of Saskatchewan. All data on rectal cancer patients will be collected at these sites. Data will be collected from surgeon surveys. Pathology data and patient data will also be collected by the study personnel for these same patients.

After agreeing to participate in this study, you will be contacted by email to conduct an initial intake survey. Subsequently, after performing a rectal cancer surgery, you will be asked to complete a surgery-specific survey about the specific rectal cancer excision. All surveys are expected to take approximately 10-20 minutes to complete. This intact survey collects basic information about you including demographics, training, and practices.

The patient-specific survey will be sent to you shortly after surgery is completed and ideally completed prior to pathology report released. Completion of this survey will take approximately 5-15 minutes. This survey seeks to identify your perception of type of mesorectal excision, factors that made mesorectal excision more/less difficult. You will be asked to complete one patient-specific survey per patient operated on for Rectal Cancer. You may be asked to complete 10-20 of these surveys. The higher volume surgeons will perform the most rectal cancer surgeries and thus will be asked to complete the greatest number of surveys.

You need only answer those questions they are comfortable with answering.

CONFIDENTIALITY:
In Saskatchewan, the Health Information Protection Act (HIPA) defines how the privacy of personal health information must be maintained so that patient privacy will be respected.

Your confidentiality and patient confidentiality will be respected. All surgeon and patient data will be coded and will be presented in a de-identified form in all publications of the data.
No information that discloses your identity will be released or published without your specific consent to the disclosure. All data will be stored securely in the Principal Investigator's office for five years after the study has been completed, after which time all hard copies and electronic copies will be permanently and confidentially destroyed.

Research records and medical records identifying patients may be inspected in the presence of the Investigator or his or her designate and the University of Saskatchewan Research Ethics Board for the purpose of monitoring the research. However, no records, which identify patients or surgeons by name or initials, will be allowed to leave the Investigators' offices. The results of this study may be presented in a scientific meeting or published, but your identity will not be disclosed.

POSSIBLE RISKS:
If you choose to participate in this study, the main risk is the inadvertent releases of your personal information. The researchers have taken measures to protect the privacy of your information and this risk is considered very small.

POSSIBLE BENEFITS:
If you choose to participate in this study, there will be no direct benefit to you. However, the information collected could help patients undergoing rectal cancer surgeries and may be informative to surgeons such as yourself who perform mesorectal excisions.

RIGHT TO WITHDRAW:
Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. There will be no penalty or loss of benefits if you choose to withdraw. If you choose to enter the study and then decide to withdraw later, all data collected about you during your enrolment will not be retained for analysis. Your right to withdraw from the study will apply until data collection is complete.

WHAT WILL THE STUDY COST ME?
You will not incur any costs or receive any payments for participating in the study.

HOW CAN I OBTAIN MORE INFORMATION ABOUT THIS STUDY?
If you provide your email address when you complete the intake survey, you will be emailed a summary of the results upon the conclusion of this study.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?
Thank you for considering participation in this study. If you have any questions or concerns, please feel free to contact either Dr. Gary Groot (306-653-3366 or garygroot@gmail.com) or Dr. Julie Kickbush (306-716-2803 or jab177@mail.usask.ca). .

This research project was reviewed and approved on ethical grounds through a harmonized review process by the University of Saskatchewan and Regina Qu'Appelle Health Region Research Ethics Boards. Any questions regarding your rights as a participant may be addressed to that committee through the University of Saskatchewan Research Ethics Office at 306-966-2975(out of town participants may call 1-888-966-2975).

PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: **Surgical Practices in Saskatchewan: Researching A Surgeon's Perception of Total Mesorectal Excision**

- I have read the information in this consent form.
- I understand the purpose and procedures and the possible risks and benefits of this study.
- I was given sufficient time to think about it.
- I had the opportunity to ask questions and have received satisfactory answers.
- I understand that I am free to withdraw from this study at any time for any reason and the decision to stop taking part will not affect my future relationships or career.
- I give permission to the use and disclosure of my de-identified information collected for the research purposes described in this form.
- I understand that by clicking "I AGREE" I do not waive any of my legal rights.

If you agree to participate in this study, please click "I AGREE" below.

If you do not wish to participate in this study, you may close this tab in your browser to exit the survey.

I AGREE (you will be taken to the intake survey on the next page)

Study Title: Evaluation of Rectal Surgery with respect to Total Mesorectal Excision in Saskatchewan

Principle Investigators: Dr. Gary Groot (Department of General Surgery: Saskatoon).

Dr. Julie Kickbush (General Surgery Resident: Saskatoon).

Intake Questionnaire of Participating Surgeons:

Demographics

1. Name:
    i. First:
    ii. Last:
2. Email:
3. Hospital(s) of Practice:
    i. Location:
    ii. Location:
    iii. Location:
4. Years in Practice:

Training

5. Training
    a. Medical Degree:
        1. Year Completed:
    b. Surgical Training:
        1. Year Completed:
    c. Subspecialty or Fellowship Training:

1. Yes/No:
2. Fellowship Name:
3. Year Completed:

Research Questions:

6. Would you be interested in receiving **a copy of the final results** of this study?
    1. Yes/No
7. If you are interested in receiving a copy, how would you like the final results sent to you:
    i. Mail:
        a. Mailing Address:
        b. City:
        c. Province: SK
        d. Postal Code: _ _ _-_ _ _
    ii. Electronic Copy by Email:
        a. Email Address:
    iii. Other:
        a. Fax: (306) _ _ _-_ _ _ _
8. Would you like to receive your own personal results of the study?
    1. Yes/No
9. If you are interested in receiving a copy, how would you **like your personal results** sent to you:
    i. Mail:
        a. Mailing Address:
        b. City:
        c. Province: SK
        d. Postal Code: _ _ _-_ _ _

ii. Electronic Copy by Email:

    a. Email Address:

iii. Other:

    a. Fax: (306) _ _ _-_ _ _ _

Study Title: Evaluation of Rectal Surgery with respect to Total Mesorectal Excision in Saskatchewan

Principle Investigators: Dr. Gary Groot (Department of General Surgery: Saskatoon).

Dr. Julie Kickbush (General Surgery Resident: Saskatoon).

Patient-related Questionnaire of Participating Surgeons:

Surgeon Demographics:

1. Surgeon Identification Code:

Patient Date of Procedure:

2. Month:
3. Day:
4. Year:
5. Time:

Note to surgeons: If you are uncertain which patient this survey is for (e.g. if more than one surgery is performed in one day), please contact the research personnel by phone and we can confirm which patient this is for (Dr. Julie Kickbush: (306) 716-2803).

Procedure:

6. Procedure performed:

Definition of Rectal cancers: based on CAP (College of American Pathologists) Guidelines (2012):

The rectum, with approximate dimensions measuring 12 cm long from the anal verge, constitutes three anatomical segments:

-Upper third: "covered by peritoneum on anterior and lateral surfaces"

-Middle third: "covered by peritoneum only on anterior surface"

-Lower third: "has no peritoneal covering"

"The transition from sigmoid to rectum is marked by the fusion of the tenia coli of the sigmoid to form the circumferential longitudinal muscle of the rectal wall approximately 12 to 15 cm from the dentate line. The rectum is defined clinically as the distal large intestine commencing opposite the sacral promontory and ending at the anorectal ring, which corresponds to the proximal border of the puborectalis muscle palpable on digital rectal examination. When measuring below with a rigid sigmoidoscope, it extends 16 cm from the anal verge." (CAP Guidelines, p. 15-16, 2012).

7. Was this procedure performed for Rectal Cancer?:

-Yes/No

8. Was this procedure performed with curative intent?

-Yes/No

Mesorectal Excision:

The definition of various types of mesorectal excision, as provided by the College of American Pathologists is as follows:

Incomplete

-Little bulk to the mesorectum
-Defects in the mesorectum down to the muscularis propria
-After transverse sectioning, the circumferential margin appears very irregular

Nearly Complete

-Moderate bulk to the mesorectum
-Irregularity of the mesorectal surface with defects greater than 5 mm, but none extending to the muscularis propria
-No areas of visibility of the muscularis propria except at the insertion site of the levator ani muscles

Complete

-Intact bulky mesorectum with a smooth surface
-Only minor irregularities of the mesorectal surface
-No surface defects greater than 5 mm in depth

-No coning towards the distal margin of the specimen
-After transverse sectioning, the circumferential margin appears smooth

9. **Based on the guidelines above, would you classify this resection as:**

    i. **Incomplete**

    ii. **Nearly complete**

    iii. **Complete**

10. **Where there any factors that made the total mesorectal excision more difficult? If so, what factors made the TME more difficult?**

    -

11. **Where there any factors that made the total mesorectal excision less difficult? If so, what factors made the TME less difficult?**

    -

Guidelines from CAP, p. 19, 2012:
http://www.cap.org/apps/docs/committees/cancer/cancer_protocols/2013/Colon_13protocol_3300.pdf

Study Title: Evaluation of Rectal Surgery with respect to Total Mesorectal Excision in Saskatchewan

Principle Investigators: Dr. Gary Groot (Department of General Surgery: Saskatoon).

Dr. Julie Kickbush (General Surgery Resident: Saskatoon).

Patient Data Collection Form:

Personal Information:

1. **Identification Code:**
2. **Sex:**
    i. **Male**
    ii. **Female**
3. **Age at time of procedure:**

Medical History:

4. **Past Medical History:**
    i. **Oncologic history:**
        1. **Type**
        2. **Date of diagnosis:**
    ii. **Diabetes**
    iii. **Hypertension**
    iv. **Obesity**
    v. **Other:**

5. **Past Surgical History:**
    i. **Bowel surgeries**
        1. **Appendectomy**
        2. **Previous bowel resections**
    ii. **Abdominal surgeries**
        1. **Cholecystectomy**
        2. **Hysterectomy**
    iii. **Other:**
6. **Body Mass Index:**
    i. **Height**
    ii. **Weight**

Oncologic History:

7. **Preoperative Chemotherapy:**
    i. **Yes/No:**
    ii. **Date:**
    iii. **Type:**
    iv. **Cycles:**
8. **Preoperative Radiotherapy**
    i. **Yes/No:**
    ii. **Date:**
    iii. **Amount:**
    iv. **Number of Treatments:**

Surgical Information:

9. **Hospital Site Code:**
10. **Surgeon Identification Code:**

11. **Date of procedure:**
    i. **Day:**
    ii. **Month:**
    iii. **Year:**
12. **Procedure Performed:**
    i. **Open/ Laparoscopic/ Laparoscopic Assisted/ Other (e.g. Transanal excision)**
13. **Complications:**
14. **Estimated Blood Loss:**

<u>Pathology Results:</u>

15. **Preoperative pathology:**
    i. **Biopsy type:**
    ii. **Date:**
    iii. **Pathology result:**
16. **Post-operative pathology:**
    i. **Final diagnosis:**
    ii. **Tumor Location:**
        a. **Distance from peritoneal reflection:**
        b. **Distance from anal verge:**
    iii. **Tumour Size:**
        a. **Greatest Dimension:**
        b. **Additional Dimensions:**
    iv. **T-stage**
        a. **T-stage:**
    v. **N-stage**
        a. **N-stage:**

b. **Number of lymph nodes sampled:**

c. **Number of lymph nodes involved:**

vi. **M-stage**

a. **M-stage:**

vii. **Total Mesorectal Classification:**

a. **Complete**

b. **Nearly complete**

c. **Incomplete**

d. **Cannot be determined**

viii. **Margins:**

a. **Closest Margin:**

i. **Distance of invasive carcinoma from closest margin**

ii. **Location**

b. **Proximal Margin:**

i. **Cannot be assessed/ Uninvolved by invasive carcinoma/ Involved by invasive carcinoma**

c. **Distal Margin:**

i. **Cannot be assessed/ Uninvolved by invasive carcinoma/ Involved by invasive carcinoma**

d. **Circumferential Margin**

i. **Cannot be assessed/ Uninvolved by invasive carcinoma/ Involved by invasive carcinoma**

e. **Deep Margin:**

i. **Cannot be assessed/ Uninvolved by invasive carcinoma/ Involved by invasive carcinoma**

f. **Mucosal Margin:**

i. **Cannot be assessed/ Uninvolved by invasive carcinoma/ Involved by invasive carcinoma**

ix. **Histologic Type:**

a. **Adenocarcinoma**

b. **Squamous cell carcinoma**

c. **Other:**

x. **Histologic Grade:**

a. **Not applicable**

b. **Cannot be determined**

c. **Low-grade (well differentiated to moderately differentiated)**

d. **High-grade (poorly differentiated to undifferentiated)**

xi. **Microscopic Tumour Extension:**

a. **No invasion into lamina propria**

b. **Intramucosal carcinoma, invasion of lamina propria/muscularis mucosae**

xii. **Lymphovascular invasion:**

a. **Not identified**

b. **Present**

c. **Indeterminate**

xiii. **Perineural Invasion:**

a. **Not identified**

b. **Present**

c. **Indeterminate**

xiv. **Type of Polyp in Which Invasive Adenocarcinoma Arose:**

a. **Tubular Adenoma**

b. **Villous Adenoma**

c. **Tubulovillous Adenoma**

d. **Traditional Serrated Adenoma**

e. **Sessile Serrated Adenoma**

f. **Hamartomatous Polyp**

g. **Indeterminate**

h. **Other**

xv. **Ancillary Studies:**

a. **Special Stains/results:**

b. **Microsatellite instability:**

c. **Immunohistochemistry for mismatch repair proteins:**

d. **Mutational analysis:**

xvi. **Treatment Effect:**

a. **No prior treatment**

b. **Present**

1. **No residual tumour**
2. **Moderate response**
3. **Minimal response**

c. **No definite response identified**

d. **Not known**